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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,849	10/22/2001	Mitchell E. Reff	P 0280728 2000-30-0513A	7677

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,849	REFF, MITCHELL E.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

8:00

1. Applicant's election without traverse of Group II in the reply filed on 6/28/2005 is acknowledged.

2. Claims 1-8,14-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/28/2005.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 13 are indefinite in that they refer to nonelected claim 1.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method of deleting or depleting CD20 positive cells, does not reasonably provide enablement for modulating CD20 positive cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The prior art recognizes that a chimeric antiCD20 of the IgG1 isotype can be used to deplete or delete CD20 positive cells (see Reff et al.). The prior art recognizes that constant region domains mediate antibody effector function and that IgG1 and IgG3 constant region isotype antibodies would be expected to have similar effector properties (see WO 98/37099, page 15). Thus, it would be expected that a chimeric antiCD20 of

the IgG3 isotype can be used to deplete or delete CD20 positive cells. However, the term "modulate" would encompass increasing or decreasing the number of Cd20 positive cells. In view of the aformentioned teachings, it would appear that the claimed method could be not used for increasing the number of CD20 positive cells because it would be expected that treatment with the antibody recited in the claims would only lead to CD20 cell deletion or depletion.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 9-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Grillo-Lopez et al. (WO 00/27433).

Grillo-Lopez et al. teach in vivo administration of chimeric antiCD20 antibody of the IgG3 isotype (aka with IgG3 constant domains) to purge/reduce (aka deplete) CD20 positive B cell lymphoma (malignant B cells)(see claims 1,2, page 6, lines 16-21, page 4). It is an inherent property of the method that depletion occurs via the mechanisms recited in claim 13 because the antibody in the prior art is of the same isotype of that recited in the claim (IgG3) wherein antibody effector function is mediated by the IgG3 constant domains.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (US Patent 5,736,137) in view of Reff et al. (WO 98/37099).

Anderson et al. teach in vivo administration of chimeric antiCD20 antibody containing human constant regions to deplete CD20 positive B cell lymphoma (malignant B cells) in humans (see abstract, columns 6-7, column 10, penultimate paragraph). Anderson et al. disclose use of antiCD20 antibody of the IgG1 isotype (IgG1 human constant regions, C2B8) and the advantageous effector properties of said antibody (see Examples). The art recognized that the constant regions mediate the effector function of antibodies (for example see Anderson et al., fourth paragraph from the bottom). The C2B8 antibody mediates ADCC and CDC (see columns 23 and 24). Anderson et al. do not teach use of a antiCD20 antibody of the IgG3 isotype. Reff et al. teach that human gamma-3 constant domains (aka IgG3 isotype) have been shown to mediate the same effector functions as human gamma-1 (aka IgG1 isotype) (see page 15, first complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Anderson et al. teach in vivo administration of chimeric antiCD20 antibody containing human constant regions to deplete CD20 positive B cell lymphoma, the use of antiCD20 antibody of the IgG1 isotype (IgG1 human constant regions, C2B8) and the advantageous effector properties of said antibody whilst Reff et al. teach that human gamma-3 constant domains (aka IgG3 isotype) have been shown to mediate the same effector functions as human gamma-1 (aka IgG1 isotype). One of ordinary skill in the art would have been motivated to do so because Anderson et al. taught that the use of antiCD20 antibody of the IgG1 isotype (IgG1 human constant regions, C2B8) and the advantageous effector properties of said antibody whilst Reff et al. teach that human gamma-3 constant domains (aka IgG3 isotype) have been shown to mediate the same effector functions as human gamma-1 (aka IgG1 isotype).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600